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Hart-Scott-Rodino & Chevron Step Zero: Can the FTC Target the Pharmaceutical Industry?

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INTRODUCTION

In 2013, the Federal Trade Commission amended the Premerger Notification Program developed by the Hart-Scott-Rodino Act to "provide a framework for determining when a transaction involving the transfer of rights to a patent or part of a patent in the pharmaceutical [industry] . . . is reportable under the Hart Scott Rodino Act."[1] Specifically, the Federal Trade Commission (FTC) amended §§ 801.1 and 801.2 of 16 C.F.R. § 801 to codify an analysis structure that makes exclusive patent licensing agreements in the pharmaceutical industry reportable asset acquisitions.[2]

Serious questions exist, however, as to whether the FTC has authority under the Hart-Scott-Rodino Act to promulgate rules that only apply to a single industry. Furthermore, the justifications offered by the FTC for its disparate treatment of the pharmaceutical industry have been called into question. The agency's decision to single out the pharmaceutical industry could be deemed arbitrary and capricious in violation of the Administrative Procedure Act, if the disparate treatment is not based on reasonable grounds. A finding that would result in the agency action being erased from the law as it currently exists.

Beyond whether it is legally permissible to single out a single industry under the Hart-Scott-Rodino Act of 1976 (HSR Act), additional policy concerns are associated with the implementation of the new amendments. In a highly competitive industry with constantly changing science, the potential for a transaction to be delayed while awaiting a decision from the FTC, consuming large amounts of time and money is a serious issue that will surely be taken into account when relevant agreements are being contemplated. While little doubt exists that regulation is necessary, regulatory costs can clog the developmental pipelines that allow small drug developers to team with larger entities capable of ensuring new drugs meet their full potential.

With those concerns in mind, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed suit against the FTC in the District of Columbia, challenging the FTC's authority to regulate a single industry, as well as the FTC's compliance with the Administrative Procedure Act (APA).[3] Judge Howell of the District Court for the District of Columbia dismissed the suit on summary judgment pursuant to Federal Rule of Civil Procedure 56 after affording the commission the exceptionally high deferential standard

1. Premerger Notification; Reporting and Waiting Period Requirements, 78 Fed. Reg. 68,705 (Nov. 15, 2013) (codified at 16 C.F.R. Part 801).

2. *See id.*

3. *See* Pharm. Research and Mfrs. of Am. v. Fed. Trade Comm'n, No. 13-1974, 2014 WL 2431242 (D.D.C. May 30, 2014).

announced in *Chevron, U.S.A., Inc. v. NRDC, Inc*.[4] PhRMA is currently appealing the decision. While the district court engaged in what is commonly known as the "Chevron two-step," it failed to consider Chevron "step-zero." The Court may have afforded the FTC less deference and undertaken a more stringent examination of the FTC's actions, potentially resulting in different finding, had it considered step zero.

This comment will contemplate whether the District Court in *Pharmaceutical Research and Manufacturers of America v. Federal Trade Commission*, afforded the FTC proper deference in upholding the agency's actions or if a different standard should have been used. Finally, this comment will consider the effects the amendment might have on the pharmaceutical industry as well as larger questions about the interaction of intellectual property law, antitrust law, and administrative regulation. Ultimately, the outcome of the PhARMA litigation will not only determine the appropriate level of deference afforded the FTC's actions, but will affect tens of thousands of people, if not more. If the recent amendments to the HSR Act stand, compliance costs will increase and the time it takes to get new, life-saving drugs to patients will increase.

I. OPERATION AND AMENDMENT OF THE HART-SCOTT-RODINO ACT

A. Origins, Purpose, and Operation of the Hart-Scott Rodino Act

The Federal Trade Commission's stated mission is to protect consumers and the American economy from anti-competitive or deceptive practices with potential to harm the competitive process.[5] Outside of its ability to regulate unfair competition practices through § 2 of the Federal Trade Commission Act, the FTC's authority to regulate anti-competitive practices is specified in the Clayton Act[6] and the Clayton Act's amendment, the Hart-Scott-Rodino Act of 1976 (HSR Act).[7] Specifically, the Clayton Act provides that "no person . . . shall acquire the whole or any part of the assets of another . . . where . . . the effect of such acquisition may be substantially to lessen competition."[8]

The HSR Act of 1976 amended the Clayton Act to include section 7A, which granted the FTC authority to preemptively block proposed mergers and

4. Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837 (1984).

5. Fed. Trade Comm'n, *About the FTC*, FTC.GOV, http://www.ftc.gov/about-ftc (last visited Dec. 31, 2014).

6. Clayton Antitrust Act, 15 U.S.C. § 18 (2012).

7. Hart-Scott-Rodino Act, 15 U.S.C. § 18a (2012).

8. Clayton Antitrust Act § 18.

acquisitions.[9] The pre-clearance process, known as the "premerger notification program,"[10] requires companies participating in a qualifying merger to present the proposed transaction to the FTC before consummation.[11] The FTC has thirty to sixty days to investigate whether the transaction is anticompetitive in a way that violates US law.[12] If a transaction is deemed anticompetitive, the FTC initiates legal action to obtain an injunction that will block consummation of the transaction.[13] Historically, the FTC has analyzed asset acquisitions, by determining reportability of a transaction under a "make, use, and sell" analysis.[14]

This assessment has also included transfers of patent rights.[15] Under that model, reportability of a transaction turned on whether exclusive rights to make, use, or sell the subject of patent changed hands.[16] Many transactions, however, are now structured to allow the licensor to retain limited manufacturing rights or other "co-rights" to develop, promote, market, or commercialize the product with and for the sole benefit of the licensee.[17] Thus, the transactions evade FTC scrutiny under the make, use, and sell analysis because the licensor in these transactions is not transferring exclusive rights.[18]

This transaction structure could be viewed as an attempt to take advantage of a loophole, allowing companies to engage in anticompetitive transactions while avoiding FTC review.[19] Reasons exist, however, to believe the new transaction structure serves a more legitimate purpose. As the FTC noted, the Premerger Notification Office frequently sees these transactions when an innovator patents a new drug, but cannot bear the costs of the testing and FDA

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9. Hart-Scott-Rodino Act § 18a.

10. *See* Hart-Scott-Rodino Act § 18a.

11. *Id.* §18a(b), (e)(1)(A).

12. *Id.* §18a(e)(1)(A).

13. *Id.* §18a(f).

14. *See* Premerger Notification; Reporting and Waiting Period Requirements, 78 Fed. Reg. 68,705, 68,706 (Nov. 13, 2013) (codified at 16 C.F.R. Part 801).

15. In SCM Corp. v. Xerox, 645 F.2d 1195, 1210 (2d Cir. 1981), the Second Circuit held that "a patent is a form of property . . . and thus an asset, there seems little reason to exempt patent acquisitions from scrutiny."

16. Premerger Notification; Reporting and Waiting Period Requirements, 78 Fed. Reg. 68,705, 68,706 (Nov. 15, 2013) (codified at 16 C.F.R. Part 801).

17. *See* 78 Fed. Reg. 68,707—08 (Nov. 15, 2013) (codified at 16 C.F.R. Part 801).

18. *See id*. at 68,706.

19. *See* Memorandum from Burrell to the Fed. Trade Comm'n (Oct. 25, 2012) *available at* http://www.ftc.gov/sites/default/files/documents/public_comments/16-cfr-part-801-premerger-notification-reporting-and-waiting-period-requirements-project-no.p989316-561795-00005/561795-00005-84907.pdf.

approval process.[20] For those innovators an exclusive licensing agreement presents an opportunity for a greater financial return via revenue sharing than the innovator could receive from a patent sale.[21]

B. Exercising New Power Pursuant to the Hart-Scott-Rodino Act

The HSR Act, grants the FTC authority to define the terms used in the Act[22] or "prescribe such others rules as may be necessary and appropriate to carry out the purposes of [that] section."[23] In 2013, the FTC amended title 16 of the Code of Federal Regulation's §§ 801.1 and 801.2.[24]

The amendment added paragraphs (o), (p), and (q) to § 801.1.[25] Those three paragraphs provide key definitions for the terms used in paragraph (g), which applies only to the pharmaceutical industry.[26] The definitions are strategically structured to enable application to the pharmaceutical industry based on assertions made by the FTC during the rulemaking process.[27]

Paragraph (o), defines "all commercially significant rights," as "the exclusive rights to a patent that allow only the recipient of the exclusive patent rights to use the patent in a particular therapeutic area."[28] Paragraph (p), in turn defines "limited manufacturing rights," as "the rights retained by a patent holder to manufacture the products covered by a patent when all other exclusive rights to the patent within a therapeutic area (or specific indication within a therapeutic area) have been transferred to the recipient of the patent rights."[29] "Co-rights," are then defined to mean "shared rights retained by the patent holder to assist the recipient of the exclusive patent rights in developing and commercializing the product covered by the patent . . . [including], but are not limited to, co-development, co-promotion, co-marketing, and co-commercialization."[30]

Finally, the amendment added paragraph (g) to section 801.2.[31] Paragraph

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20. *See* Premerger Notification; Reporting and Waiting Period Requirements, 78 Fed. Reg. 68,705, 68,706 (Nov. 15, 2013) (codified at 16 C.F.R. Part 801).

21. *See id*. at 68,708.

22. Hart-Scott-Rodino Act, 15 U.S.C. § 18a(d)(2)(A) (2012).

23. *Id.* §18a(d)(2)(C).

24. Premerger Notification; Reporting and Waiting Period Requirements, 78 Fed. Reg. 68,705, 68,712 (Nov. 15, 2013) (codified at 16 C.F.R. Part 801).

25. *Id.*

26. *Id.*

27. *See* Premerger Notification; Reporting and Waiting Period Requirements, 78 Fed. Reg. 68,705 (Nov. 15, 2013) (codified at 16 C.F.R. Part 801).

28. *Id.* at 68,712–13.

29. *Id.*

30. *Id.* at 68,713.

31. *Id.*

(g)—applicable only to "NAICS Industry Group 33254" (an FTC categorization encompassing the pharmaceutical industry)—then uses those terms in a way that triggers reporting requirements when patent rights are transferred.[32] The most substantive portion of the addition reads:

> [p]atent rights are transferred if and only if all commercially significant rights to a patent, as defined in §801.1(o), for any therapeutic area (or specific indication within a therapeutic area) are transferred to another entity. All commercially significant rights are transferred even if the patent holder retains limited manufacturing rights, as defined in §801.1(p), or co-rights, as defined in §801.1(q).[33]

The effect of this paragraph is to make exclusive patent licenses that convey some but not all rights to "make, use, and sell," in the pharmaceutical industry reportable.[34] Specifically, paragraph (g) targets transactions in which the patent holder retains limited manufacturing rights or any other co-right.[35]

II. THE FTC'S AUTHORITY TO REGULATE A SINGLE INDUSTRY

It is the exclusive application of paragraph (g) to the pharmaceutical industry and the justifications offered by the FTC that most trouble critics.[36] The pre-merger notification process can be costly, time consuming, and add additional uncertainty to qualifying transactions; making it unsurprising that the amendment faced harsh opposition from those most directly affected by its terms.[37] Specifically, it is the exclusive application of paragraph (g) to the pharmaceutical industry and the justifications offered by the FTC that most troubles critics.[38]

A. Searching for Authority to Regulate a Single Industry

The FTC lacks authority to target a single industry with additional

32. *See id.*

33. *Id.*

34. *Id.* at 68,706.

35. *Id.*

36. *See* Memorandum from Pharmaceutical Research and Mfrs. of America to the Fed. Trade Comm'n (Oct. 25, 2012) *available at* http://www.ftc.gov/sites/default/files/documents/public_comments/16-cfr-part-801-premerger-notification-reporting-and-waiting-period-requirements-project-no.p989316-561795-00004/561795-00004-84972.pdf; Memorandum from Varner to the Fed. Trade Comm'n (Oct. 25, 2012) *available at* http://www.ftc.gov/sites/default/files/documents/public_comments/16-cfr-part-801-premerger-notification-reporting-and-waiting-period-requirements-project-no.p989316-561795-00004/561795-00004-84972.pdf.

37. *See id*.

38. *See id.*

burdens, because the HSR Act is an act of general application, applying to all "person[s]" not explicitly exempted by or pursuant to the Act.[39] The starting premise of the HSR Act is that "no person shall acquire . . . any assets of any other person unless both persons . . . unless both . . . file notification"[40] The HSR Act, however, provides three groups of exemptions from the filing requirement.[41] First, the Act imposes a threshold exemption, ensuring small transactions that are unlikely to have an anticompetitive effect on the much larger market will not be subject to FTC review.[42] Next, Congress provided a set of class exemptions.[43] Congress explicitly listed twelve classes of transactions it has determined are unlikely to have anticompetitive effects, and thus, need not be reviewed by the FTC.[44] Finally, Congress granted the FTC special authority to exempt classes of persons and acquisitions "not likely to violate antitrust laws."[45] In sum, Congress intended the HSR Act to place the same burden on all persons and transactions unless either Congress, or—in special circumstances—the FTC deemed a specific class of persons or transactions unlikely to violate the antitrust laws. Section "d" of the HSR Act, which is especially important for analyzing the FTC's authority to regulate a single industry under the HSR Act, reads:

> (d) Commission rules
> The Federal Trade Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5, consistent with the purposes of this section—
>
> (1) shall require that the notification required under subsection (a) of this section be in such form and contain such documentary material and information relevant to a proposed acquisition as is necessary and appropriate to enable the Federal Trade Commission and the Assistant Attorney General to determine whether such acquisition may, if consummated, violate the antitrust laws; and
>
> (2) may—
>
> (A) define the terms used in this section;
>
> (B) exempt, from the requirements of this section, classes of persons, acquisitions, transfers, or transactions which are not likely to violate the antitrust laws; and
>
> (C) prescribe such other rules as may be necessary and

39. *See* Hart-Scott-Rodino Act, 15 U.S.C. § 18a (2012).
40. *Id.*
41. *Id.*
42. *Id.* §18a(a).
43. *Id.* §18a(c).
44. *See id*.
45. *Id.* §18a(d)(2)(B).

appropriate to carry out the purposes of this section.[46]

The FTC contends its authority to regulate a single industry rests in its power to define terms as well as its authority to prescribe necessary and appropriate rules.[47] It argues that the addition of paragraph "g" is simply a clarification of the definition of an asset acquisition in the context of the pharmaceutical industry, made pursuant to Section 18a (d)(2)(A) of the HSR Act.[48] In a comment submitted during the comment period, PhARMA questioned the FTC's justifications, arguing that limiting the clarification to the pharmaceutical industry does not define any term used in the Act, nor is paragraph (g) included in the Act's definition section.[49]

Secondly, the FTC argued its authority to prescribe rules "necessary and appropriate to carry out the purposes of this section."[50] To fully contemplate this second basis of alleged authority, the purpose of the referenced section must be fully understood. In the case of the HSR Act, the purpose is to implement the premerger notification program and screen which classes of persons and transactions are required to file notice before consummation of an agreement.[51] With such a broadly defined purpose, the ability to prescribe rules necessary to carry out that purpose is a very broad power, indeed. If the FTC does have authority to target a single industry, it likely comes from this broad grant of power. Use of that broad power, however, is conditioned on compliance with the Administrative Procedure Act.

B. The District Court's Application of Chevron Deference

1. District Court Decision

In 2013, PhRMA filed a lawsuit in the District of Columbia's District Court challenging the FTC's authority to regulate a single industry, as well as the FTC's compliance with the Administrative Procedure Act (APA).[52] Judge Howell afforded the FTC the exceptionally high level of deference announced

46. *Id.* §18a(d).

47. Premerger Notification; Reporting and Waiting Period Requirements, 78 Fed. Reg. 68,705, 68,709 (Nov. 15, 2013) (codified at 16 C.F.R. Part 801).

48. *Id.*

49. *See* Hart-Scott-Rodino Act § 18a.

50. Premerger Notification; Reporting and Waiting Period Requirements, 78 Fed. Reg. 68,705, 68,709 (Nov. 15, 2013) (codified at 16 C.F.R. Part 801).

51. *See* Hart-Scott-Rodino Act § 18a.

52. *See* Pharm. Research and Mfrs. of Am. v. Fed. Trade Comm'n, No. 13-1974, 2014 WL 2431242 (D.D.C. May 30, 2014).

in *Chevron, U.S.A., Inc. v. Natural Resource Defense Counsel, Inc.*[53] and granted the FTC's motion for summary judgment after raising and rejecting each of PhRMA's arguments.[54]

The district court engaged in what is commonly known as the "Chevron two-step" to determine the proper degree of deference to afford the FTC.[55] It failed, however, to consider Chevron "step-zero."[56] Had the district Court considered step zero, it may have afforded the FTC less deference and undertaken a more stringent examination of the FTC's actions, potentially resulting in different finding as to both the FTC's authority and compliance with the APA.

2. Chevron Deference & Step Zero

Development of the *Chevron* doctrine has significantly increased the frequency in which courts afford administrative interpretation of relevant statutes a high level of deference, overturning an agency action or interpretation only if it is unreasonable.[57] In *Chevron U.S.A. Inc. v. Natural Resources Defense Counsel, Inc*., the Court held that where Congress leaves gaps and ambiguities in statutes implemented by administrative agencies, an implied grant of interpretive authority.[58] The Chevron court coined a two-step analysis in which courts ask first whether the statutory language is clear and unambiguous as to the interpretation in question.[59] If the answer is no, courts then considers the soundness of the agency's interpretation.[60] The agency's interpretation need not be ingenious, rather, it must merely be reasonable.[61] This analytical structure is commonly known as the Chevron-two-step for obvious reasons, however, since the *Chevron* decision, academics and the courts alike have contemplated an additional step.[62]

This additional step, aptly named "step-zero," is the initial inquiry and

53. Chevron U.S.A. Inc. v. Natural Res. Def. Counsel, Inc., 467 U.S. 837 (1984).

54. *See Pharm. Research and Mfrs. of Am.*, 2014 WL 2431242.

55. *See id*. at *10–20.

56. *See id*.

57. Kristin E. Hickman & Thomas W. Merrill, *Chevron's Domain*, 89 GEO. L.J. 833 (2001).

58. *See Chevron*, 467 U.S. 837.

59. *Id.* at 842–43.

60. *Id.* at 843.

61. *Id.*

62. *See generally*, Hickman & Merrill, *supra* note 57; United States v. Mead Corp., 533 U.S. 218 (2000). *See also generally*, Cass R Sunstein, *Chevron Step Zero*, 92 VA. L. REV. 187 (2006); William N. Eskridge, Jr. & Lauren E. Baer, *The Continuum of Deference: Supreme Court Treatment of Agency Statutory Interpretations from Chevron to Hamdan*, 96 GEO. L.J. 1083 (2008); Lisa Schultz Bressman, *Beyond Accountability: Arbitrariness And Legitimacy in the Administrative State*, 78 N.Y.U. L. REV. 461 (2003).

determines whether courts should even turn to the Chevron two-step.[63] Advocates of "step-zero" reason that before applying the Chevron two-step, which applies only to agencies whose rule making carries the force of law, courts should inquire as to whether deference to agency action was truly Congress' intent because deference to Chevron is based on the implied authority from the legislature.[64] The Chevron two-step assumes Congressional intent, however, where it can be demonstrated that Congress did not intend to grant an administrative agency authority to make an interpretation, courts apply the less deferential *Skidmore* standard of review, as the Supreme Court did in *United States v. Mead Corp*.[65]

Thomas Merrill and Kristen Hickman also suggest that courts should adopt an exemption from Chevron deference for interpretations by agencies implicating the scope of its own authority.[66] The reasoning for the proposed exception holds that courts have never deferred to agencies on questions of their own power and it makes little sense to presume that Congress delegated an agency the authority to interpret the scope of its own authority.[67] Furthermore, if agencies have the power to define the scope of their own authority, judicial oversight will seemingly be removed from the system of checks and balances.[68]

The scope of authority exemption has not yet taken hold in the courts; however, its premature confines have begun to appear in case law.[69] In *Mississippi Power & Light v. Mississippi ex rel. Moore*, Justice Brennan argued in dissent that:

> [a]gencies do not 'administer' statutes confining the scope of their jurisdiction . . . [n]or do the normal reasons for agency deference apply . . . It is thus not surprising that this Court has never deferred to an agency's interpretation of a statute designed to confine the scope of its jurisdiction.[70]

Considering the same question more recently, in *City of Arlington v. FCC*, Chief Justice Breyer wrote in concurrence that "the existence of statutory

63. Hickman & Merrill, *supra* note 57, at 836.

64. Hickman & Merrill, *supra* note 57, at 912; Christensen v. Harris County, 529 U.S. 576, 587 (2000); *Mead Corp*., 533 U.S. at 227.

65. *See Mead Corp*., 533 U.S. 218.

66. Hickman & Merrill, *supra* note 57, at 909.

67. *Id.* at 909–10.

68. *Id.*

69. *See* Mississippi Power & Light v. Miss. ex rel. Moore, 487 U.S. 354, 386–87 (Brennan, J., dissenting); City of Arlington, Tex., v. FCC, 133 S. Ct. 1863, 1875 (2013) (Breyer, J., concurring).

70. *Mississippi Power & Light*, 487 U.S. at 386–87 (Brennan, J., dissenting).

ambiguity is sometimes not enough to warrant the conclusion that Congress has left a deference-warranting gap . . . sometimes context-specific factors will on occasion prove relevant."[71] In the same case, Chief Justice Roberts (who was joined by Justices Kennedy and Alito) in his dissenting opinion, argues that "[a] congressional grant of authority over some portion of a statute does not necessarily mean that Congress granted the agency interpretative authority over all its provisions."[72]

Case law indicates the idea that proponents of implementation of a flat exception from Chevron deference for interpretations implicating the agency's authority is still fighting an uphill battle.[73] In response to Justice Breyer's *Mississippi Power & Light* dissent, Justice Scalia wrote in his own concurring opinion "it is settled law that the rule of deference applies even to an agency's interpretation of its own . . . authority."[74] In *City of Arlington*, the majority held "[t]he dissent is correct that . . . for Chevron deference to apply, the agency must have received congressional authority to determine the particular matter at issue."[75] The Court, however, goes on to say "[w]hat the dissent . . . fails to produce is a single case in which a general conferral of rulemaking . . . authority has been insufficient to support Chevron deference for an exercise of that authority," seemingly regardless of the nature of the interpretation.[76]

Therefore, for the time being, a plaintiff hoping to avoid Chevron deference to administrative agency action should not rely solely on the argument that such deference should not apply to interpretations of scope of authority. Rather, the plaintiff should set out to demonstrate via legislative history, statutory construction, policy and language of an enabling act, that Congress did not intend to grant the agency authority to determine the particular matter at issue.

In *Pharm. Research and Mfrs. Of Am. V. Fed. Trade Comm'n*, the district court conducted a Chevron two-step analysis, however, the Court failed to consider Chevron step zero.[77] The Court ultimately determined that the FTC's actions should be afforded Chevron deference.[78] Had the Court considered

71. *City of Arlington, Tex.*, 133 S. Ct. at 1875 (Breyer, J., concurring).

72. *Id.* at 1883 (Roberts, J., dissenting).

73. *See Miss. Power & Light*, 487 U.S. at 381(Scalia, J., concurring); *City of Arlington, Tex.*, 133 S. Ct. at 1874.

74. *Miss. Power & Light*, 487 U.S. at 381 (Scalia, J., concurring).

75. *City of Arlington, Tex.*, 133 S. Ct. at 1874.

76. *Id.*

77. *See* Pharm. Research and Mfrs. of Am. v. Fed. Trade Comm'n, No. 13-1974, 2014 WL 2431242, at *10 (D.D.C. May 30, 2014).

78. *Id.*

rather than assumed Chevron step zero, the outcome may have differed. In determining whether to engage a Chevron two-step analysis, the Court should have examined the legislative history, statutory construction, policy, and language of the HSR Act to determine whether it was truly Congress' intent to delegate the FTC authority to determine its own ability to regulate a single industry. On the one hand the structure of the HSR Act, its legislative history, and comments made by one of the bill's sponsors and namesakes, strongly support a finding that Congress did not intend to grant the FTC such authority. On the other hand, section (d)(2)(C) of the HSR Act provides a broad grant of power that could be read as Congress conceding that measures not contemplated by the HSR Act may be necessary and subsequently the FTC exercised that broad power delegated to it by Congress.

A strong argument can be made that Congress did not intend to grant the FTC authority to interpret the Act as they did. If that argument is persuasive, engaging in a Chevron two-step analysis as well as the granting of Chevron deference by the district court was inappropriate. Structurally, the HSR Act's starting point is that all transactions must be presented to the PNO for approval.[79] As previously discussed, the Act goes on to provide three types of exemptions from the filing requirements in specific situations in which the class of transaction or persons in question are not likely to have an anticompetitive effect on the market for one reason or another.[80] This illustrates that the Act is set up in a way so as to require regulation, except in the special and specific cases in which either Congress or the FTC determines it is not likely that the antitrust laws will be violated. The structure is informative and indicates that Congress did not foresee nor intend the FTC to have authority to actively regulate a single industry. Rather, it seems Congress intended the FTC to have authority to exempt single industries from regulation.

The legislative history reinforces this conclusion. The congressional record reveals that the legislature considered granting the FTC power to regulate a single industry.[81] An early draft of the law included a power for the FTC to require filings "from particular . . . industries."[82] Congress, however, intentionally removed that language from the bill, deciding the FTC should not wield such a power.[83] Commenting on the deletion, the bill's namesake and sponsor, Representative Rodino, explained, "in the view of the House

79. Hart-Scott-Rodino Act, 15 U.S.C. § 18a(a) (2012).
80. *See id.* §18a(a)–(d).
81. *See* 122 CONG. REC. 29,342 (Sept. 8, 1976).
82. 122 CONG. REC. 29,342 (Sept. 8, 1976).
83. *See* 122 CONG. REC. 30,877 (Sept. 16, 1976).

conferees, the coverage of this bill should be decided by Congress – not the FTC."[84] Furthermore, while the language of the bill was being negotiated in the Senate, an amendment was considered that would have granted the FTC authority to "promulgate rules of general or special applicability."[85] The Senate decided not to grant such authority, removing the clause as the House had done with a similar clause, because it appeared to give the FTC rule making authority "either appropriately dealt with in other sections, or are so broad and general as to threaten to undermine an otherwise carefully structured statutory scheme."[86] Again, indicating that the HSR Act was intentional structured to provide the FTC with certain powers and to withhold others.

In sum, Congress structured the HSR Act in a way that gave the FTC authority and discretion to exempt specific and special classes of persons and transactions from the filing requirement of the premerger notification program. Additionally, Congress made the intentional decision not to grant the FTC authority to regulate a single industry. Viewed this way, it seems unlikely that Congress decided not to grant the FTC authority while simultaneously making an implied grant of the exact same authority.

On the other hand, arguments can be made that refute that conclusion. Section (d)(2)(C) of the HSR Act authorizes the FTC to "prescribe other rules as may be necessary and appropriate to carry out the purposes of this section."[87] One might argue that while the structure of the HSR Act indeed suggests that the FTC's typical role is to make exemptions from the filing requirement, the broad grant of authority made in section (d)(2)(C) is effectively Congress' concession that over time, rules Congress did not contemplate may become necessary. This could be true, especially in light of section (d)(2)(B). Section (d)(2)(B) of the HSR authorizes the FTC to make special exemptions where transactions are not likely to violate antitrust laws.[88]

Thus, it could be argued that the HSR Act is structured in a way that begins with all persons and transactions falling subject to regulation unless an exemption is applied, included within that structure is a power to grant special exemptions, and yet, Congress included an additional power to prescribe "other" rules. Clearly, "other rules" would be different from those rules included in the act. Therefore, section (d)(2)(B) grants the FTC authority to take action other than exempting persons or transactions from regulation, such

84. 122 CONG. REC. 30,877 (Sept. 16, 1976) (statement of Rep. Rodino).
85. Antitrust Improvements Act, S. 1284, 94th CONG. § 7A (b)(4)(A)(1976).
86. 122 CONG. REC. 15,812 (1976).
87. Hart-Scott-Rodino Act, 15 U.S.C. § 18a(d)(2)(C) (2012).
88. *Id.* §18a(d)(2)(B).

as actively subjecting individual industries to regulation. If a court finds this second argument persuasive, it will hold that the FTC was merely exercising the authority delegated to it by Congress and its rule-making decisions with the force of law will be afforded Chevron deference.

Because Chevron deference is based in implied congressional delegation of authority, the issue turns on congressional intent. An argument can be made that both the structure of the HSR Act and the broad catch-all grant of authority in section (d)(2)(C), indicate congressional intent that the FTC have the means to take "other" "necessary and appropriate" action as it saw fit. Stated another way, Congress intended that the FTC would interpret section (d)(2)(C) in a way that would enable the commission to carry out the purposes of the Act. If not for the intentional and explicit decision Congress made not to grant the FTC authority to regulate single industries, such an argument would likely be persuasive. It cannot be said that Congress intended to withhold such a power from the FTC, while simultaneously intending to grant the same power to the FTC. Chevron deference is a very difficult hurdle for petitioners to overcome, and on a question of Congressional intent, where explicit language indicating a contrary Congressional intent, such a level of deference is not appropriate. Such a finding is not, however, a damning result for the FTC action or agencies more generally. Where Chevron deference is not applicable, agency actions will still be afforded *Skidmore* deference.[89]

III. THE EFFECTS OF THE INTERSECTION OF INTELLECTUAL PROPERTY LAW, ANTITRUST LAW, AND ADMINISTRATIVE REGULATION.

The premerger notification program aims to preemptively block anticompetitive activity.[90] The program also has potential to negatively impact the development of life-saving drugs if it is not implemented properly. This illustrates a larger incongruence that occurs between intellectual property rights and administrative enforcement of antitrust law. Patents are intended to incentivize innovation by ensuring that innovators will have a period of time in which they face less competition to recoup the expenses incurred in the costly research and development process. Agency enforcement of antitrust law, however, is intended to prevent or negate situations in which a market will become less competitive. These two goals and approaches to the market are strictly at odds with one another. The cost of these clashing legal doctrines can be especially high in the pharmaceutical industry, where research and development is often extremely expensive.

While a lack of regulation or oversight could lead to fewer choices and

89. United States v. Mead Corp., 533 U.S. 218, 239 (2000).

90. *See* Hart-Scott-Rodino Act § 18a.

higher prices for consumers heavily dependent on the drugs, over-zealous regulation could have the same effect.[91] If the FTC is overly aggressive in its administration of paragraph (g), administrative costs of transactions could increase significantly. In a highly competitive industry with constantly changing science, the potential for a transaction to get tied up in the FTC's antitrust office, consuming large amounts of time and money, is a serious issue manufacturers will take into account when contemplating potential partnerships. While there is little doubt that regulation is necessary, it is important to ensure that regulatory costs do not clog the developmental pipelines that allow small drug developers to team with larger entities capable of ensuring new drugs meet their full potential.

Increased regulatory costs may simply force the industry to be more selective in what drugs are worth the financial risk. The problem is evident, however, when one considers the possibility that the drug that finally cures cancer, Alzheimer's disease, or AIDS will start as a long shot that simply cannot overcome the potential risks and costs associated with the FTC's new requirements. A drug that would have saved thousands or even millions of lives could be lost before its potential is realized.

CONCLUSION

The FTC's recent amendment of the Hart-Scott-Rodino Act targets a single industry, something the FTC has never done pursuant to the HSR Act. The Commission's authority to take such action and whether it did so in compliance with the APA is questionable. PhRMA's lawsuit challenging the rule may have been on track to invalidate the new rule, however, after the District Court failed to apply *Chevron* step zero and afforded the agency action significantly more deference than it may have been due, the FTC was granted summary judgment.[92]

PhRMA has filed notice of appeal and is currently awaiting its next day in court.[93] If the appellate court properly applies *Chevron* step zero rather than assume the answer, as the district court seemingly did, the *Skidmore* deference standard is likely to be applied – resulting in a more stringent examination of the claims.

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91. Burrell, *supra* note 19, at 5.

92. Pharm. Research and Mfrs. of Am. v. Fed. Trade Comm'n, No. 13-1974, 2014 WL 2431242 (D.D.C. May 30, 2014).

93. *Civil Docket for Case #: 1:13-cv-01974-BAH*, (last updated July 30, 2014, 10:03 AM), available online at https://www.bloomberglaw.com/search/results/fc7597ff5de47944c2b95c80565b8e54/document/X1Q6N5OAHCO2?search32=C9P6UQR5E9FN6PB1E9HMGNRKCLP6QF9H78OJ6BB3EOMJ0C9P6SQ2QGI190TJMRJFBTKMQS2VE1K74OBJCLPJQC9R7DJ6IU2VC9NMUR2VE5QMASJP7KOG.

This case will have an impact upon more than the level deference afforded to administrative action. This case could impact tens of thousands of lives, if not more. If the new amendment stands, it will undoubtedly increase compliance costs and delay the process of getting new drugs to market. On the other hand, the new regulation could – as it is intended to do – make the market for prescription drugs more competitive, ensuring people can afford the drugs they so badly need. Which of these considerations will outweigh the others? What are the magnitudes of their respective impacts? If the regulation stands, what role will human discretion in the administration of the new amendments play? We simply cannot know until we see how the amendment operates in practice and how pharmaceutical manufacturers respond.

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